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REMARKS
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**Status of Claims and Application**

No amendments have been made to currently pending claims 1, 2, 4-8, 11-15 and 19-24 and a Notice of Appeal has concurrently been filed with this response.

**35 U.S.C. 103(a) rejections**

- (1) Claims 1, 2, 4-8, 11-15, 18 and 19 were rejected by the examiner as being obvious over Giacomoni (WO 96/26711). The applicants' request reconsideration of this rejection for the following reasons:

The Examiner briefly responded to applicants' previous response by addressing the use of the phrase "consisting essentially of". However, regardless of how the Examiner elects to interpret the scope of this phrase, the Examiner has not adequately addressed how, when considering both the claimed invention and Giacomoni reference "as a whole", the facts of the case support the proposition that it is more likely than not that the present claims are *prima facie* obvious.

The "as a whole" consideration is one of the four tenets of patent law which must be adhered to when applying 35 U.S.C. 103 (see MPEP 2141). As stated in the previous response, the Giacomoni reference only mentions rosaceae amongst a large Markush-like list of potential uses.

Moreover, MPEP 2142 establishes that "[t]o reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. ***Knowledge of applicant's disclosure must be put aside in reaching this determination...***" (emphasis added). Applying this standard to the present application, the applicants' continue to assert that one of ordinary skill in the art when presented with the Giacomoni reference ***but without having the applicants' claims to act as a roadmap*** would not find the applicants' claimed method of treating rosaceae to be obvious given that Giacomoni's teachings is not only buried in a Markush-like group of potential uses but reads more like an invitation to experiment rather than an affirmative teaching. It is from this backdrop, that the applicants' assert that the Examiner has not met the burden by a preponderance of the evidence that the applicants' claims are obvious in light of Giacomoni.

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#### Reprint of Applicants' response of 5 January 2004

##### **Background**

The claims as amended are directed toward a method of treating rosacea, however, the first ten lines of the examiner's rejection appear directed more towards a rejection of a composition claim. While it is understood that it is necessary to disclose that elements of the composition used in the applicants method claims are also taught by Giacomoni, the examiner concedes that "While the Giacomoni reference encompasses the claimed method of treating rosacea by applying to a patient a NO-synthase inhibitor-containing composition, it is deficient in the sense that it does not provide guidance as to selecting rosacea among various other skin conditions."

The applicants agree with the examiner's assessment of the method of treating rosacea claims up to this point but disagree with the rationale that the examiner uses to assert that the applicants' claimed invention is obvious over Giacomoni.

##### **Context of Giacomoni's teaching is not directed toward treating rosacea**

The evidence that Giacomoni teaches the treatment of rosacea, the examiner directs attention to a passage in Giacomoni which teaches that his compositions "are ideal for use" in the treatment of "dermatological complaints associated with a keratinisation disorder relating to differentiation and proliferation, particularly for treating...rosaceous acne."

To a layman, the examiner's comment would appear to suggest an almost explicit teaching from within Giacomoni as there is no further description about the passage from which the quoted text was obtained. However, this is not an accurate depiction of the context within which Giacomoni made his disclosures and one of ordinary skill in the art reading the same passage referred to by the examiner would not come to the conclusion that the applicants claimed invention is obvious over Giacomoni.

Determination of obviousness requires consideration "as a whole" of both the applicants' invention and the invention of the prior art and does not allow for improper picking and choosing elements to meet the requirements of the applicants claims. For the record, the passage from Giacomoni is reproduced below with the examiner's quotations being in bold and italics:

"The pharmaceutical compositions according to the invention ***are ideal for use*** in the following areas of treatment, these treatments being particularly well adapted when these compositions contain retinoids:

- 1) for treating ***dermatological complaints associated with a keratinisation***

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*disorder relating to differentiation and proliferation, particularly for treating common blackheads, polymorphous and **rosaceous acne**, nodulocystic acnes, conglobata, senile acnes, secondary acnes such as solar acne, medicinal or professional acne;*

- 2) for treating other types of keratinisation disorders, particularly ichtyoses, ichtyosiform conditions, Darrier's disease, palmoplantar disease, palmoplantar keratodermias, leucoplasias and leucoplasiform conditions, cutaneous lichen of the (oral) mucous membrane;
- 3) for treating other dermatological complaints associated with a keratinisation disorder with an inflammatory and/or immuno-allergic component, and in particular all forms of psoriasis, whether it be cutaneous, mucous or ungula, and even psoriatic rheumatism, or even cutaneous atopia, such as eczema or respiratory atopia, or even gingival hypertrophy; the compounds may also be used in certain inflammatory complaints not presenting a keratinisation disorder;
- 4) for treating all dermal or epidermal proliferations, whether benign or malignant, whether or not of viral origin, such as common verrucas, plain verrucas or verruciform epidermodysplasia, oral or florid papillomatoses, and the proliferations that may be induced by ultraviolet radiation, particularly in the case of baso- and spinocellular epitheliomas;
- 5) for treating other dermatological disorders such as bullate dermatoses and collagenic diseases;
- 6) for treating certain ophthalmological disorders, particularly corneopathies;
- 7) for repairing or controlling ageing of the skin , whether photo-induced or chronological, or fro reducing pigmentations and actinic keratoses, or any pathologies associated with chronological or actinic aging;
- 8) for preventing or curing stigmata of epidermal and/or dermal atrophy induced by local or systemic corticosteroids, or any other form of cutaneous atrophy;
- 9) for preventing or treating scarring disorders or for preventing or repairing stretch marks;

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- 10) for controlling disorders of the sebaceous function, such as acne hyperseborrhoea or simple acne or seborrhea;
- 11) in the treatment of or prevention of cancerous or pre-cancerous conditions;
- 12) in the treatment of inflammatory complaints such as arthritis;
- 13) in the treatment of any complaint of viral origin affecting the skin or generally;
- 14) in the prevention or treatment of alopecia;
- 15) in the treatment of dermatological or general disorders with an immunological component;
- 16) in the treatment of disorders of the cardiovascular system, such as arteriosclerosis."

Giacomoni's invention is primarily directed toward using their claimed compositions to reduce the skin irritant effect of topically applied cosmetic or pharmaceutical substances (see e.g. Giacomoni's abstract). The passage reproduced above at best represents unsubstantiated conjecture by Giacomoni. At worst, Giacomoni's teaching represents improper picking and choosing as Giacomoni presents a vast array of ailments to be treated without providing any direction or guidance for any of them. It has previously been held that when confronted with such a dizzying array of choices, the effect is that none of the choices are obvious without further direction (see e.g. *In re Rice*, 178 USPQ 478, 480 (CCPA 1973) - "...the board said, referring to the appellant's ingredients, 'It should be noted that an infinite number of combinations is possible.' Accepting that as an approximation to the truth, we fail to see the obviousness in devising appellant's.....[invention] as claimed." )

Furthermore, the claims as amended state that the compositions used in the claimed method of treatment of rosacea consist essentially of NO-synthase inhibitors and salts thereof. Even if it could be shown that the above passage from Giacomoni was enabling and provided adequate guidance towards the treatment of rosacea, it is only in the context of "...these treatments being particularly well adapted **when these compositions contain retinoids...**" Giacomoni does not teach or suggest that the broader scope of treatments would be effective in the absence of retinoids.

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***Preponderance of evidence standard for obviousness is not supported by Giacomoni***

MPEP 2142 states:

"The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness [page 2100-123]...The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of "a preponderance of evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it.

With regard to the rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e. the reference teachings establish a *prima facie* case of obviousness) is more probable than not."

While the applicants concede that the evidence of record is less than 100% for non-obviousness, the applicants hold that the evidence in support of a holding of *prima facie* obviousness presented by the examiner does not meet the greater than 50% standard (i.e. preponderance of evidence) required to maintain a *prima facie* holding of obviousness especially when viewed in light of the teachings of Giacomoni for the broader methods of use and the requirement that retinoids be part of the compositions used in Giacomoni's method of use.

- (2) Claims 20-24 were rejected by the examiner as being obvious over Giacomoni (WO 96/26711) in view of Breton et al. (U.S. Patent 5,795,574).

The applicants' response with respect to Giacomoni for claims are considered to be repeated here and should the rejections for these claims be withdrawn, the rejection of claims 20-24 should also be withdrawn.

In the event that the rejection is maintained, the applicants extend the "as a whole" arguments to the application of Breton et al. in combination with Giacomoni. It is clear from the Breton reference that when considering their invention as a whole it is directed toward the use of "at least one extract from at least one non-photosynthetic filamentous bacteria" and in many respects is even broader with regard to potential compounds (see col. 9, lines 12-37) to be used in their pharmaceutical composition as well as their potential uses (see e.g. col. 1, lines 43-67 and col. 2, lines 45-55).

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Merely finding references which have the elements of the applicants' invention is insufficient to establish *prima facie* obviousness. As stated in *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998):

"As this court has stated, 'virtually all [inventions] are combinations of old elements...Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.' *Sensotronics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996).'" *Rouffet*, 149 F.3d at 1357, 47 USPQ2d 1457.

Applicants' continue to assert that since the MPEP 2143.03 requires that all claim limitations be taught in order to establish *prima facie* obviousness, one of ordinary skill in the art would not have found the applicants' claimed invention to be obvious when presented with the Giacomoni and Breton et al. references but without having benefit of the applicants' claims before them to direct which elements to select and combine from the references.

#### Closing

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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#### CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 (10 pages) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 8 June 2004

By: Agata Glinska  
Agata Glinska